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| APPLICATION NO.                        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|--|-------------|----------------------|-------------------------|------------------|--|
| 10/655,847                             | 09/05/2003  | William Gaarde       | ISPH-0766               | ISPH-0766 7081   |  |
| 7590 11/12/2004                        |             |                      | EXAM                    | EXAMINER         |  |
| Licata & Tyrrell P.C.                  |             |                      | BOWMAN, AMY HUDSON      |                  |  |
| 66 E. Main Street<br>Marlton, NJ 08053 |             |                      | ART UNIT                | PAPER NUMBER     |  |
| ,                                      |             |                      | 1635                    |                  |  |
| •                                      |             |                      | DATE MAILED: 11/12/2004 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)                     |  |  |  |
|---|--|----------------------------------|--|--|--|
|   |  |                                  |  |  |  |
| Office Action Summary   | 10/655,847   | GAARDE ET AL.                    |  |  |  |
| Office Action Summary   | Examiner   | Art Unit                         |  |  |  |
|   | Amy H Bowman   | 1635                             |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |                                  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                                  |  |  |  |
| Status  |  |                                  |  |  |  |
| 1) Responsive to communication(s) filed on  |  |                                  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ Thi   | s action is non-final.                                 |                                  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |                                  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |                                  |  |  |  |
| Disposition of Claims   |  |                                  |  |  |  |
| 4) Claim(s) 1-11 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-11 are subject to restriction and/or   | ewn from consideration.  election requirement.         |                                  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |  |                                  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |  |                                  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |                                  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |                                  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·   | ZAMINOT. NOTO THO UTGOTION OTHOGO                      | 7.00011 01 101111 1 1 0 1 0 2 .  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |                                  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |                                  |  |  |  |
| Attachment(s)   |  |                                  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | 4) Interview Summary                                   |                                  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06 Paper No(s)/Mail Date   | Paper No(s)/Mail D  5) Notice of Informal F  6) Other: | ate Patent Application (PTO-152) |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

The claims are subject to restriction under 35 U.S.C. 121 as follows. The claims are not considered to be a proper genus/Markush. See MPEP 803.02-PRACTICE RE MARKUSH-TYPE CLAIMS- If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush grouping the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPO 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPO 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 7169, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, an antisense sequence has not been specified for claim 1. As the oligonucleotide targeted to a nucleic acid encoding PPAR-delta has been recited in the claims, it broadly reads on all versions of sequences possible to target a nucleic acid molecule encoding PPAR-delta. Although the antisense claimed targets and modulates expression of PPAR-delta, each sequence is considered to be unrelated,

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since each antisense sequence is structurally and functionally independent for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of a PPAR-delta, and each antisense, upon binding to a PPAR-delta nucleic acid, functionally modulates (increases or decreases) the expression of the gene to varying degrees (specification, table 1). Please specify a particular PPAR-delta antisense sequence, preferably identified by a SEQ ID, so that it may be searched by nucleotide sequence. Note this is not a species election.

Additionally, claim 9 broadly reads on all PPAR-delta sequences. Please select a specific PPAR-delta target sequence, preferably by SEQ ID, as specified in claim 1, so that it may be searched by nucleotide sequence.

Claim 9 links all of the inventions, each sequence comprising its own invention as outlined above. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 9. Upon allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim is/are presented in a continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:30 am – 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as

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general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman Examiner Art Unit 1635

JOHN L. LEGUYADER
SUPERVISORY PATENT EXAMINED
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